

16072687

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510(k) Summary or 510(k) Statement

510(k) Summary

1. Submitter Information:

NOV 25 2008

Covidien
Energy-based Devices
Formerly known as Valleylab, a Division of Tyco Healthcare LP
5920 Longbow Drive
Boulder, CO
Contact: Philip E. Ake
Senior Regulatory Associate
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2. Name of Device

Trade name: Valleylab Microwave Ablation Generator
Common/Classification name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

3. Predicate Devices

The Valleylab Microwave Ablation Generator is substantially equivalent to the following legally marketed medical devices:

- VivaWave Microwave System (K011676)
- Cool-tip™ RF System (K053290)

4. Device Description

The Valleylab Microwave Ablation Generator is designed to provide microwave power for the ablation of soft tissue in medical procedures. It was cleared for commercial distribution (K011676) by demonstrating substantial equivalence to existing Radiofrequency and Microwave Ablation systems.

The Microwave Ablation Generator is designed to be used with proprietary microwave antennas (cleared in K011676 and K032702) which are placed directly into the tissue to be ablated. The Valleylab Microwave Ablation Generator is a non-sterile electrical device that is not intended to contact the patient.

The Microwave Ablation Generator is used with a pump to circulate cooling fluid (sterile saline) to the antennas, and an optional integrated cart. The device's power output and duration (time) are controlled by the user via manual controls on the front

panel of the generator. The display on the front of the device shows power (watts), duration of power delivery (minutes and seconds), and elapsed time.

The antenna is connected to the generator and radiates power to the tissue under treatment. The antennas are provided sterile, for single use only. The shaft of each antenna is made of insulated stainless steel. Three antennas of different lengths are available for use in percutaneous procedures, and a single length antenna for surgical procedures. The active portion of the antenna is 3.7cm in length for all models. The percutaneous antennas are cooled by circulating sterile saline through the antenna. The surgical antennas are not internally cooled. The system pump circulates fluid from a reservoir to the antenna through sterile tubing. Sterile fluid is confined within the antenna and tubing, and does not contact the patient.

5. Intended Use

The Valleylab Microwave Ablation Generator is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

The MW Ablation Generator is not intended for use in cardiac procedures

6. Summary of Technology Characteristics

The Valleylab Microwave Ablation Generator operates at 915 MHz. The generator is capable of operating up to 60 W. The amount of power delivered depends on the antenna used and is controlled by the generator firmware. The user has the ability to select the desired power and time limits within the system specifications. The generator firmware is responsible for the system error codes.

The technological characteristics of the Valleylab Microwave Ablation generator are not being modified; this 510(k) is for a change to the intended use of the device.

The original Intended Use of the MW Ablation generator was for use on soft tissue. This submission expands the intended use to include partial or complete ablation of non-resectable liver tumors. The Cool-tip generator intended use includes ablation of liver tumors.

7. Summary Non-clinical testing

Bench Testing was conducted on bovine livers and in-vivo testing on porcine livers to compare the ablation size and geometry of lesions created by the Microwave Ablation Generator and the Cool-tip™ RF System. The testing included single and multiple antenna comparisons. The lesions were evaluated histologically and physically. The testing revealed that in some instances there was a difference in lesion size. However, the lesions that are generated by both systems have similar pathologic and imaging characteristics.

Other testing included: thermal profile testing, performance testing, evaluation of ablation characteristics next to vasculature, an evaluation of the device to the current versions of the relevant safety standards, and software testing.

8. Summary of Clinical testing

A review of the existing studies have shown that the use of the system to be clinically safe and effective for ablation of liver tumors.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2008

Covidien,
% Mr. Philip E. Ake
Senior Regulatory Associate
5920 Longbow Drive
Boulder, Colorado 80301-3299

Re: K072687

Trade/Device Name: Valleylab Microwave Ablation Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: November 14, 2008
Received: November 17, 2008

Dear Mr. Ake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Philip E. Ake

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072687

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Valleylab Microwave Ablation Generator _____

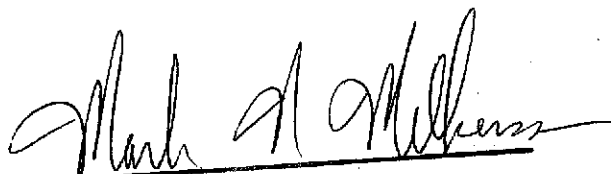
Indications for Use:

The Valleylab Microwave Ablation Generator is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072687